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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,604	07/10/2000	James Say	12008.20USC1	1097

7590 12/21/2001

Attention of J Scot Wickhem
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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 12/21/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,604

Applicant(s)

SAY ET AL.

Examiner

Navin Natnithithadha

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 127-170 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 127-152, 159 and 162-170 is/are rejected.
- 7) ☒ Claim(s) 153-158, 160 and 161 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

2. The disclosure is objected to because of the following informalities:

On page 10, line 19, page 16, line 22, page 17, line 2, page 26, line 24, page 29, line 9, page 35, line 24, the Patent Application data and PCT Patent Application data must be updated.

Appropriate correction is required.

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 127-140, 148-152, 160-170 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurnik et al, US 5,827,183.

In regards to claims 127, 160-162, and 167-170, Kurnik discloses an electrochemical sensor for determining the concentration of an analyte (see col. 1, lines 18-31), comprising: working electrode 4; electrode 5; gel 3 containing enzyme glucose oxidase (see col. 14, lines 28-30); and

“a mask having an opening therein wherein the mask is positioned between the skin and the working electrode; transporting a chemical through the skin and ionically conductive material whereby the mask blocks flow to the catalytic surface except for flow substantially axial to the catalytic surface;” (see claim 1).

As to claims 127, 134-140, and 148-152, Kurnik does not specifically teach a substrate. However, it is inherent that a substrate is used to support the electrodes and mask.

As to claims 128-131, 165, and 166, Kurnik discloses, generally, an ionically conductive material is used for the electrodes (see col. 7, lines 36-39).

As to claims 132, 133, 163, and 164, Kurnik teaches one or more electrodes in Figs. 2A and 2B.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 141-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurnik et al, US 5,827,183, and further in view of Hill et al, US 5,509,410.

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Claims 127 was rejected under 35 U.S.C. 102(b) as discussed above.

As to claims 141-147, Kurnik does not teach an electron transfer agent.

However, Hill teaches electrochemical sensor including an enzyme electrode assembly 17 and an electron transfer mediator (see col. 2, lines 1-14). It would have been obvious to one of ordinary skill in the art to modify Kurnik's invention with Hill's invention to effect electron transfer to in the active electrode.

8. Claims 159 and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurnik et al, US 5,827,183.

Claims 127 was rejected under 35 U.S.C. 102(b) as discussed above.

As to claim 159, Kurnik does not teach use of an anticlotting agent to dispose on a portion of the substrate that is configured for implantation. However, it is well known in the art to use heparin on implantable devices.

As to claim 162, Kurnik does not teach the pore size, or "openings 2" in the mask layer 3, having 3 to 20,000 nm in diameter. However, it would be obvious to one skilled in the art to modify Kurnik's "mask" layer to have more openings 2 with the parameters for the opening sizes claimed because it is a matter of engineering choice.

Allowable Subject Matter

9. Claims 153-158, 160, and 161 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

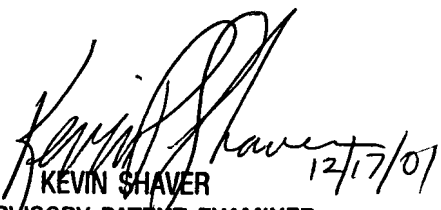
Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3337 for regular communications and (703) 746-3337 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2701.

Navin Natnithithadha
Patent Examiner
GAU 3736
December 17, 2001


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
12/17/01

Attachment for PTO-948 (Rev. 03/01, or earlier)

6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.